OCT 2 5 2002

PHILIPS

Philips Medical Systems

510(k) Summary

K022788

Philips "Harmony" Release 1

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I General Information

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway 98021-8431 Bothell Washington USA
Contact Person	Lynn T. Harmer
Telephone Number:	425-478-7312
Prepared (date):	August 20, 2002
Device Name:	Philips Harmony Release 1
Classification Name:	System, Image Processing
Regulation number	892.2050
Classification:	Class: II
ProCode:	LLZ
Common/Usual Name:	Workstation
Predicate Devices:	Philips Inturis Suite Philips EnConcert (Formerly HP Echo Image Management System)

II Information Supporting Substantial Equivalence Determination

System Description:

Philips "Harmony" software is a suite of DICOM products containing scalable levels of modular software programs, designed to perform the necessary functions required for the import/export/storage/archiving/review/analysis/reporting and database management of digital cardiovascular images within the cardiology domain.
It allows multiple users quick access to, and exchange of specific and/or multiple cardiology exams.
Because of the open architecture, the "Harmony" software will run on Intel based commercial hardware under Microsoft Windows based operating systems.
Together with the modular design it allows the user to tailor the image import, archive and communications solution to his particular budgetary and performance needs and the number of modalities and reporting and/or viewing sites he decides to connect.
PHILIPS will guarantee stability and (different levels of) performance when used with specific hardware configurations and network infrastructure.

The following packages are marketed:

- Standalone Workstation
- Integrated Workstation network solution
- Base, Advanced and Premium network solutions

These software packages will be delivered on a set of CD-ROMs, which contain the installation application, the application software, the service software and an electronic copy of the instructions for use.

Intended Use:

Philips "Harmony" software package is an integrated multimodality image and information system designed to perform import, export, storage, archiving, review, analysis, reporting and database management of digital medical images.

Substantial equivalence:

Predicate devices
The Philips "Harmony" software release 1 is substantially equivalent to

a. Inturis Suite (K994210)
Philips Medical Systems, Best , The Netherlands

b. EnConcert (K954668)
Philips Medical Systems, Andover MA, USA
(formerly HP Echo Image Management System
Hewlett Packard Co, Andover MA, USA)

Comparison matrix / technological characteristics

Characteristics	PHILIPS Inturis Suite R2.2	PHILIPS EnConcert B.0	PHILIPS "Harmony" R1
Operating System	Windows NT Windows 2000	Windows NT	Windows NT/2000/XP
Memory Requirement	256 MB (minimum) 512 MB (recommended)	128 MB (minimum) 256 MB (recommended)	512 MB (minimum) 1 GB (recommended)
Image Source	DICOM 3.0 SCU DICOM 3.0 CD-ROM	DICOM 3.0 SCU DSR-TIFF I/F DICOM 3.0 Media	DICOM 3.0 SCU DSR-TIFF I/F DICOM 3.0 Media
Connectivity	Philips HSDII DICOM Store SCP DICOM Verification DICOM Storage Commit Card. Info System I/F	Philips SONOS DICOM Store SCP	Philips HSDII Philips SONOS DICOM Store SCP DICOM Verification DICOM Storage Commit Card. Info System I/F
Display Rate	Up to 30 fps	Up to 30 fps	Up to 60 fps
Multiple Windows	Yes	Yes	Yes
Image Display Controls Digital Zoom Window (contrast) Level (brightness)	 Yes Yes Yes	 Yes Yes Yes	 Yes Yes Yes
Annotation	Yes	Yes	Yes
Image Export	BMP, JPG, AVI DICOM Store SCU DICOM Q/R SCP DICOM Q/R SCU	BMP, AVI DICOM Store SCU	BMP, JPG, AVI DICOM Store SCU DICOM Q/R SCP DICOM Q/R SCU
Network Access	Yes	Yes	Yes
Regulatory Status	K994210	K954668	Proposed

Safety information:

No new hazards are introduced by the development of "Harmony" software. Hazards known during the lifecycle of the predicate devices Inturis Suite and EnConcert are again considered. The results of the hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2002

Mr. Lynn T. Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Everett Highway
BOTHELL WA 98021-8431

Re: K022788
Trade/Device Name: Harmony
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 21, 2002
Received: August 22, 2002

Dear Mr. Harmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): ~~Unknown~~ K022788

Device Name: "Harmony"

Indications for Use::

"Harmony", is a suite of products comprised out of scalable levels of modular software programs, designed to perform the necessary functions required for the import, export, storage, archiving, review, analysis, reporting and database management of multimodality digital medical images.

"Harmony" software will run on Intel based commercial hardware under Microsoft Windows based operating systems.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyran

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022788

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)